

James R. Condo (#005867)
Amanda Sheridan (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
JCondo@swlaw.com
ASheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Richard.North@nelsonmullins.com
Matthew.Lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

KENDRICK TAYLOR, an individual,

Plaintiff,

Case No. CV-15-2463-PHX-DGC

v.

C. R. BARD, INC., a New Jersey
corporation, and BARD PERIPHERAL
VASCULAR, INC., (a subsidiary and/or
division of defendant C. R. BARD, INC.)
an Arizona corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

Defendants.

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (collectively “Defendants”), through undersigned counsel, hereby file their answer and defenses to Plaintiff Kendrick Taylor’s (“Plaintiff”) First Amended Complaint (“Plaintiff’s Complaint”) as follows:

1. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that they are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants.

PARTIES

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of Plaintiff’s Complaint and, on that basis, deny them.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them.

4. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the Southern District of Alabama.

5. Defendants deny that Bard is a Delaware corporation. Defendants admit that Bard is a New Jersey corporation and that Bard is authorized to do business, and does business, in the State of Alabama. Defendants further admit that Bard owns a facility where vena cava filters, including the Meridian™ Filter System, are manufactured. Defendants deny any remaining allegations contained in Paragraph 5 of Plaintiff’s Complaint.

6. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Alabama. Defendants further admit that BPV is a wholly owned subsidiary of Bard that designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and

distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 6 of Plaintiff's Complaint.

JURISDICTION AND VENUE

7. Defendants do not contest that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in this Court.

8. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the Southern District of Alabama.

FACTUAL ALLEGATIONS

9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 9 of Plaintiff's Complaint.

10. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny the remaining allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendants deny the allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. Defendants deny the allegations contained in Paragraph 12 of Plaintiff's Complaint.

1 13. Defendants deny the allegations contained in Paragraph 13 of Plaintiff's
2 Complaint.

3 14. Defendants deny the allegations contained in Paragraph 14 of Plaintiff's
4 Complaint.

5 15. Defendants deny the allegations contained in Paragraph 15 of Plaintiff's
6 Complaint.

7 16. Defendants lack knowledge or information sufficient to form a belief as to the
8 truth of the allegation regarding the time frame when inferior vena cava filters were first
9 introduced on the market or the identity of manufacturers of inferior vena cava filters.
10 Defendants deny any remaining allegations of Paragraph 16 of Plaintiff's Complaint.

11 17. Defendants admit that inferior vena cava filters are intended to prevent injury or
12 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
13 that inferior vena cava filters may be designed for permanent placement, temporary
14 placement, or both. Defendants deny any remaining allegations of Paragraph 17 of Plaintiff's
15 Complaint.

16 18. Defendants admit that the inferior vena cava is a large vein that receives blood
17 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
18 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
19 human health, including sometimes death. Defendants deny any remaining allegations of
20 Paragraph 18 of Plaintiff's Complaint.

21 19. Defendants admit that certain people are at an increased risk for the
22 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
23 to form a belief as to the truth of the allegations as stated regarding the various risk factors
24 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
25 deny them. Defendants deny any remaining allegations of Paragraph 19 of Plaintiff's
26 Complaint.

1 20. Defendants admit that patients at a high risk for developing deep vein
2 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
3 including but not limited to the medications listed in Paragraph 20 of Plaintiff's Complaint.
4 Defendants further admit that inferior vena cava filters may also be used to treat patients who
5 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
6 lack knowledge or information sufficient to form a belief as to the truth of any remaining
7 allegations contained in Paragraph 20 of Plaintiff's Complaint and, on that basis, deny them.

8 21. Defendants lack knowledge or information or information sufficient to form a
9 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
10 were first introduced on the market. Defendants also lack knowledge or information
11 sufficient to form a belief as to the truth of the allegation regarding the time frame when
12 optional or retrievable filters came to be marketed or the other allegations regarding optional
13 or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®,
14 G2®, G2® Express, Eclipse™, and Meridian™ Filters were cleared by the FDA for optional
15 use as retrievable inferior vena cava filters. Defendants deny any remaining allegations
16 contained in Paragraph 21 of the Complaint.

17 22. Defendants admit that the Recovery® Filter was cleared by the FDA for
18 permanent placement on November 27, 2002, pursuant to an application submitted under
19 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. The allegations pertaining to the
20 requirements of Section 510(k) contained in Footnote 1 are conclusions of law to which no
21 answer is required. Defendants deny any remaining allegations contained in Paragraph 22 of
22 Plaintiff's Complaint, including all sub-parts thereof and including any allegations contained
23 in Footnote 1.

24 23. Defendants admit that the Recovery® Filter was cleared by the FDA for
25 retrievable placement on July 25, 2003, pursuant to an application submitted under Section
26 510(k) of the Food, Drug and Cosmetic Act of 2005. Defendants deny any remaining
27 allegations contained in Paragraph 23 of Plaintiff's Complaint.
28

1 24. Defendants deny the allegations contained in Paragraph 24 of Plaintiff's
2 Complaint.

3 25. Defendants admit that the Recovery® Filter consists of twelve, shape memory
4 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
5 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
6 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
7 allegations contained in Paragraph 25 of Plaintiff's Complaint.

8 26. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
9 manufacture of the Recovery® Filter and further admits that Nitinol contains shape memory.
10 However, to the extent Paragraph 26 purports to cast liability either directly or indirectly
11 upon Defendants, said Paragraph is expressly denied.

12 27. Defendants admit that the Recovery® Filter was designed to be inserted
13 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
14 delivered via an introducer sheath, which is included in the delivery system for the device.
15 Defendants are without knowledge or information sufficient to form a belief as to the truth of
16 the allegations contained in Paragraph 27 of Plaintiff's Complaint regarding the typical
17 practices of physicians, including physician methods for determining successful implantation
18 of the Recovery® Filter, and, on that basis, such allegations are denied. Defendants deny any
19 remaining allegations of Paragraph 27 of Plaintiff's Complaint.

20 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
21 Complaint, including any allegations contained in Footnote 2.

22 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's
23 Complaint.

24 30. Defendants deny the allegations contained in Paragraph 30 of Plaintiff's
25 Complaint.

26 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's
27 Complaint.

1 32. Defendants admit that there are various well-documented complications that
2 may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard
3 states that there are incidents related to the occurrence of known complications associated
4 with every manufacturer of inferior vena cava filters. By way of further response, Bard states
5 that information available in the public domain, including the FDA MAUDE database, is not
6 a comprehensive analysis of all instances of such complications. Defendants deny the
7 remaining allegations of Paragraph 32 of Plaintiff's Complaint, and all sub-parts thereof.

8 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
9 Complaint.

10 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
11 Complaint.

12 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's
13 Complaint.

14 36. Defendants admit that there are various well-documented complications that
15 may occur as a result of the fracture, migration, tilt, and/or perforation of any inferior vena
16 cava filter. Defendants further admit that it is well documented that many instances of filter
17 fracture, migration, tilt, and/or perforation result in no complications whatsoever but, rather,
18 are completely asymptomatic. By way of further response, Bard states that there are incidents
19 related to the occurrence of known complications associated with every manufacturer of
20 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 36 of
21 Plaintiff's Complaint, including all sub-parts thereof.

22 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's
23 Complaint.

24 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's
25 Complaint.

26 39. Defendants admit that, as part of their continuing efforts to constantly evaluate
27 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
28

1 continually striving to improve the life-saving performance of those devices. The G2®,
2 G2®X, Eclipse™, and Meridian™ filters were developed in furtherance of those efforts.
3 Defendants deny the remaining allegations contained in Paragraph 39 of Plaintiff's
4 Complaint.

5 40. Defendants admit that, as part of their continuing efforts to constantly evaluate
6 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
7 continually striving to improve the life-saving performance of those devices. The G2® Filter
8 was developed in furtherance of those efforts. Defendants deny the remaining allegations
9 contained in Paragraph 40 of Plaintiff's Complaint.

10 41. Defendants admit the G2® Filter System was cleared by the United States Food
11 and Drug Administration pursuant to an application submitted under Section 510(k) of the
12 Food, Drug and Cosmetic Act in 2005. Defendants admit that the G2® Filter was originally
13 cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was
14 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.
15 Defendants deny any remaining allegations contained in Paragraph 41 of Plaintiff's
16 Complaint, including any allegations contained in Footnote 3.

17 42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's
18 Complaint.

19 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's
20 Complaint.

21 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
22 Complaint.

23 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
24 Complaint.

25 46. Defendants admit that there are various well-documented complications that
26 may occur as a result of the fracture, migration, tilt, and/or perforation of any inferior vena
27 cava filter. Defendants further admit that it is well documented that many instances of filter
28

1 fracture, migration, tilt, and/or perforation result in no complications whatsoever but, rather,
2 are completely asymptomatic. By way of further response, Bard states that there are incidents
3 related to the occurrence of known complications associated with every manufacturer of
4 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 46 of
5 Plaintiff's Complaint, including all sub-parts thereof.

6 47. Defendants admit that there are various well-documented complications that
7 may occur as the result of the fracture of any inferior vena cava filter. Bard states that there
8 are incidents related to the occurrence of known complications associated with every
9 manufacturer of inferior vena cava filters. By way of further response, Bard states that
10 information available in the public domain, including the FDA MAUDE database, is not a
11 comprehensive analysis of all instances of such complications. Defendants deny the
12 remaining allegations of Paragraph 47 of Plaintiff's Complaint.

13 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
14 Complaint.

15 49. Defendants admit the G2® Express Filter System was cleared by the United
16 States Food and Drug Administration pursuant to an application submitted under Section
17 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining
18 allegations contained in Paragraph 49 of Plaintiff's Complaint.

19 50. Defendants admit the G2®X Filter System was cleared by the United States
20 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
21 the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining allegations
22 contained in Paragraph 50 of Plaintiff's Complaint.

23 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
24 Complaint.

25 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
26 Complaint.

1 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
2 Complaint.

3 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's
4 Complaint.

5 55. Defendants admit that, as part of their continuing efforts to constantly evaluate
6 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
7 continually striving to improve the life-saving performance of those devices. The Eclipse™
8 Filter was developed in furtherance of those efforts. Defendants deny the remaining
9 allegations contained in Paragraph 55 of Plaintiff's Complaint.

10 56. Defendants admit the Eclipse™ Filter System was cleared by the United States
11 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
12 the Food, Drug and Cosmetic Act in 2010. Defendants further admit that, as part of their
13 continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the
14 ever-changing state-of-the-art, they are continually striving to improve the life-saving
15 performance of those devices. The Eclipse™ Filter was developed in furtherance of those
16 efforts. Defendants deny any remaining allegations contained in Paragraph 56 of Plaintiff's
17 Complaint.

18 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
19 Complaint.

20 58. Defendants admit the Meridian™ Filter System was cleared by the United
21 States Food and Drug Administration pursuant to an application submitted under Section
22 510(k) of the Food, Drug and Cosmetic Act in 2011. Defendants deny any remaining
23 allegations contained in Paragraph 58 of Plaintiff's Complaint.

24 59. Defendants admit that, as part of their continuing efforts to constantly evaluate
25 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
26 continually striving to improve the life-saving performance of those devices. The Meridian™
27 Filter was developed in furtherance of those efforts. Defendants further admit that a nickel-
28

1 titanium alloy named Nitinol is used in the manufacture of the Meridian™ Filter. Defendants
2 deny the remaining allegations contained in Paragraph 59 of Plaintiff's Complaint.

3 60. Defendants deny the Recovery® Filter System, the G2® Filter System,
4 Eclipse™ Filter System, or Meridian™ Filter were unreasonably dangerous or defective in
5 any manner. Defendants admit that there are various well-documented complications that
6 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
7 Defendants further admit that it is well-documented that many instances of filter fracture
8 and/or migration result in no complications whatsoever, but, rather, are completely
9 asymptomatic. By way of further response, Bard states that there are incidents related to the
10 occurrence of known complications associated with every manufacturer of inferior vena cava
11 filters. Defendants deny the remaining allegations of Paragraph 60 of Plaintiff's Complaint.

12 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
13 Complaint.

14 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
15 Complaint.

16 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
17 Complaint.

18 64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's
19 Complaint.

20 65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's
21 Complaint, including all sub-parts thereof.

22 66. Defendants deny the allegations contained in Paragraph 66 of Plaintiff's
23 Complaint.

24 67. Defendants deny the allegations contained in Paragraph 67 of Plaintiff's
25 Complaint.

26 68. Defendants admit that there are various well-documented complications that
27 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
28

1 Defendants further admit that it is well documented than many instances of filter fracture
2 and/or migration result in no complications whatsoever but, rather, are completely
3 asymptomatic. By way of further response, Bard states that there are incidents related to the
4 occurrence of known complications associated with every manufacturer of inferior vena cava
5 filters. Defendants deny the remaining allegations of Paragraph 68 of Plaintiff's Complaint,
6 including all sub-parts thereof.

7 69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's
8 Complaint.

9 70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's
10 Complaint.

11 71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's
12 Complaint.

13 72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's
14 Complaint, including all sub-parts thereof.

15 73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's
16 Complaint.

17 74. In response to the allegations contained in Paragraph 74, Bard admits only that
18 the regulation cited in Paragraph 74 exists, and that it contains, in part, the language quoted.
19 To the extent the allegations in Paragraph 74 of Plaintiff's Complaint purport to cast liability
20 upon Defendants, either directly or indirectly, those allegations are denied.

21 75. In response to the allegations contained in Paragraph 75, Bard admits only that
22 the regulation cited in Paragraph 75 exists, and that it contains, in part, the language quoted.
23 To the extent the allegations in Paragraph 75 of Plaintiff's Complaint purport to cast liability
24 upon Defendants, either directly or indirectly, those allegations are denied.

25 76. In response to the allegations contained in Paragraph 76, Bard admits only that
26 the regulation cited in Paragraph 76 exists, and that it contains, in part, the language quoted.
27
28

1 To the extent the allegations in Paragraph 76 of Plaintiff's Complaint purport to cast liability
2 upon Defendants, either directly or indirectly, those allegations are denied.

3 77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's
4 Complaint.

5 78. In response to the allegations contained in Paragraph 78, Bard admits only that
6 the statute cited in Paragraph 78 exists. To the extent the allegations in Paragraph 78 of
7 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied.

9 79. In response to the allegations contained in Paragraph 79, Bard admits only that
10 the statute cited in Paragraph 79 exists. To the extent the allegations in Paragraph 79 of
11 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 80. In response to the allegations contained in Paragraph 80, Bard admits only that
14 the statute cited in Paragraph 80 exists. To the extent the allegations in Paragraph 80 of
15 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
16 those allegations are denied.

17 81. In response to the allegations contained in Paragraph 81, Bard admits only that
18 the regulation cited in Paragraph 81 exists. To the extent the allegations in Paragraph 81 of
19 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 82. In response to the allegations contained in Paragraph 82, Bard admits only that
22 the regulation cited in Paragraph 82 exists. To the extent the allegations in Paragraph 82 of
23 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 83. In response to the allegations contained in Paragraph 83, Bard admits only that
26 the regulation cited in Paragraph 83 exists. To the extent the allegations in Paragraph 83 of
27
28

1 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 84. In response to the allegations contained in Paragraph 84, Bard admits only that
4 the regulation cited in Paragraph 84 exists. To the extent the allegations in Paragraph 84 of
5 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
6 those allegations are denied.

7 85. In response to the allegations contained in Paragraph 85, Bard admits only that
8 the regulation cited in Paragraph 85 exists. To the extent the allegations in Paragraph 85 of
9 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
10 those allegations are denied.

11 86. In response to the allegations contained in Paragraph 86, Bard admits only that
12 the regulation cited in Paragraph 86 exists. To the extent the allegations in Paragraph 86 of
13 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
14 those allegations are denied.

15 87. In response to the allegations contained in Paragraph 87, Bard admits only that
16 the regulation cited in Paragraph 87 exists. To the extent the allegations in Paragraph 87 of
17 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 88. In response to the allegations contained in Paragraph 88, Bard admits only that
20 the regulation cited in Paragraph 88 exists. To the extent the allegations in Paragraph 88 of
21 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 89. In response to the allegations contained in Paragraph 89, Bard admits only that
24 the regulation cited in Paragraph 89 exists. To the extent the allegations in Paragraph 89 of
25 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied.

1 90. In response to the allegations contained in Paragraph 90, Bard admits only that
2 the regulation cited in Paragraph 90 exists. To the extent the allegations in Paragraph 90 of
3 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
4 those allegations are denied.

5 91. In response to the allegations contained in Paragraph 91, Bard admits only that
6 the regulation cited in Paragraph 91 exists. To the extent the allegations in Paragraph 91 of
7 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied.

9 92. In response to the allegations contained in Paragraph 92, Bard admits only that
10 the regulation cited in Paragraph 92 exists. To the extent the allegations in Paragraph 92 of
11 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 93. In response to the allegations contained in Paragraph 93, Bard admits only that
14 the regulation cited in Paragraph 93 exists. To the extent the allegations in Paragraph 93 of
15 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
16 those allegations are denied.

17 94. In response to the allegations contained in Paragraph 94, Bard admits only that
18 the regulation cited in Paragraph 94 exists. To the extent the allegations in Paragraph 94 of
19 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 95. In response to the allegations contained in Paragraph 95, Bard admits only that
22 the regulation cited in Paragraph 95 exists. To the extent the allegations in Paragraph 95 of
23 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 96. In response to the allegations contained in Paragraph 96, Bard admits only that
26 the regulation cited in Paragraph 96 exists. To the extent the allegations in Paragraph 96 of
27
28

1 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 97. In response to the allegations contained in Paragraph 97, Bard admits only that
4 the statute cited in Paragraph 97 exists. To the extent the allegations in Paragraph 97 of
5 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
6 those allegations are denied.

7 98. In response to the allegations contained in Paragraph 98, Bard admits only that
8 the regulation cited in Paragraph 98 exists. To the extent the allegations in Paragraph 98 of
9 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
10 those allegations are denied, including all sub-parts thereof.

11 99. In response to the allegations contained in Paragraph 99, Bard admits only that
12 the regulation cited in Paragraph 99 exists. To the extent the allegations in Paragraph 99 of
13 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
14 those allegations are denied.

15 100. In response to the allegations contained in Paragraph 100, Bard admits only that
16 the regulation cited in Paragraph 100 exists. To the extent the allegations in Paragraph 100 of
17 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 101. In response to the allegations contained in Paragraph 101, Bard admits only that
20 the regulation cited in Paragraph 101 exists. To the extent the allegations in Paragraph 101 of
21 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 102. In response to the allegations contained in Paragraph 102, Bard admits only that
24 the regulation cited in Paragraph 102 exists. To the extent the allegations in Paragraph 102 of
25 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied.

1 103. In response to the allegations contained in Paragraph 103, Bard admits only that
2 the regulation cited in Paragraph 103 exists. To the extent the allegations in Paragraph 103 of
3 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
4 those allegations are denied.

5 104. In response to the allegations contained in Paragraph 104, Bard admits only that
6 the regulation cited in Paragraph 104 exists. To the extent the allegations in Paragraph 104 of
7 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied.

9 105. In response to the allegations contained in Paragraph 105, Bard admits only that
10 the regulation cited in Paragraph 105 exists. To the extent the allegations in Paragraph 105 of
11 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 106. In response to the allegations contained in Paragraph 106, Bard admits only that
14 the regulation cited in Paragraph 106 exists. To the extent the allegations in Paragraph 106 of
15 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
16 those allegations are denied.

17 107. In response to the allegations contained in Paragraph 107, Bard admits only that
18 the regulation cited in Paragraph 107 exists. To the extent the allegations in Paragraph 107 of
19 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 108. In response to the allegations contained in Paragraph 108, Bard admits only that
22 the regulation cited in Paragraph 108 exists. To the extent the allegations in Paragraph 108 of
23 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 109. In response to the allegations contained in Paragraph 109, Bard admits only that
26 the regulation cited in Paragraph 109 exists. To the extent the allegations in Paragraph 109 of
27
28

1 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied, including all sub-parts thereof.

3 110. Defendants admit the Meridian™ Filter System was cleared by the United
4 States Food and Drug Administration pursuant to an application submitted under Section
5 510(k) of the Food, Drug and Cosmetic Act in 2010. Defendants deny any remaining
6 allegations contained in Paragraph 110 of Plaintiff's Complaint.

7 111. Defendants admit the Meridian™ Filter System was cleared by the United
8 States Food and Drug Administration pursuant to an application submitted under Section
9 510(k) of the Food, Drug and Cosmetic Act in 2011. Defendants deny any remaining
10 allegations contained in Paragraph 111 of Plaintiff's Complaint

11 112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's
12 Complaint.

13 113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's
14 Complaint.

15 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's
16 Complaint.

17 115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's
18 Complaint.

19 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's
20 Complaint.

21 117. Defendants are without knowledge or information sufficient to form a belief as
22 to the truth of the allegations contained in Paragraph 117 of Plaintiff's Complaint and, on that
23 basis, deny them.

24 118. Defendants are without knowledge or information sufficient to form a belief as
25 to the truth of the allegations regarding the trade name of any inferior vena cava filter
26 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
27 allegations of Paragraph 118 of Plaintiff's Complaint.
28

119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 119 of Plaintiff's Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's Complaint.

124.. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE

127. Defendants incorporate by reference their responses to Paragraphs 1-126 of Plaintiff's Complaint as if fully set forth herein.

128. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed

1 filters under the trademark Meridian™ Filter Systems. Defendants deny any remaining
2 allegations contained in Paragraph 128 of Plaintiff's Complaint.

3 129. Defendants are without knowledge or information sufficient to form a belief as
4 to the truth of the allegations regarding the trade name of any inferior vena cava filter
5 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
6 allegations of Paragraph 129 of Plaintiff's Complaint.

7 130. The allegations contained in Paragraph 130 regarding Defendants' duty are
8 conclusions of law, and no answer is required. To the extent a response is required,
9 Defendants deny the allegations. Defendants deny the remaining allegations contained in
10 Paragraph 130 of Plaintiff's Complaint.

11 131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's
12 Complaint.

13 132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's
14 Complaint, including all sub-parts thereof.

15 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
16 Complaint.

17 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
18 Complaint.

19 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
22 Complaint.

23 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
24 Complaint.

SECOND CAUSE OF ACTION**STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

138. Defendants incorporate by reference their responses to Paragraphs 1-137 of Plaintiff's Complaint as if fully set forth herein.

139. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 139 of Plaintiff's Complaint.

140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of Plaintiff's Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of Plaintiff's Complaint.

144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's Complaint.

145. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's Complaint.

146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's Complaint.

1 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's
2 Complaint.

3 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiff's
4 Complaint.

5 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's
6 Complaint.

7 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's
8 Complaint.

9 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiff's
10 Complaint.

11 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's
12 Complaint.

13 **THIRD CAUSE OF ACTION**

14 **STRICT PRODUCTS LIABILITY – DESIGN DEFECTS**

15 153. Defendants incorporate by reference their responses to Paragraphs 1-152 of
16 Plaintiff's Complaint as if fully set forth herein.

17 154. Defendants are without knowledge or information sufficient to form a belief as
18 to the truth of the allegations regarding the trade name of any inferior vena cava filter
19 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
20 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
21 the trademark Meridian™ Filter System were manufactured at that facility. Defendants
22 further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and
23 that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™
24 Filter System. Defendants deny any remaining allegations contained in Paragraph 154 of
25 Plaintiff's Complaint.

26 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's
27 Complaint.

1 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's
2 Complaint.

3 157. Defendants deny the allegations contained in Paragraph 157 of Plaintiff's
4 Complaint.

5 158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's
6 Complaint.

7 159. Defendants deny the allegations contained in Paragraph 159 of Plaintiff's
8 Complaint.

9 160. Defendants deny the allegations contained in Paragraph 160 of Plaintiff's
10 Complaint.

11 **FOURTH CAUSE OF ACTION**

12 **STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

13 161. Defendants incorporate by reference their responses to Paragraphs 1-160 of
14 Plaintiff's Complaint as if fully set forth herein.

15 162. Defendants are without knowledge or information sufficient to form a belief as
16 to the truth of the allegations regarding the trade name of any inferior vena cava filter
17 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
18 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
19 the trademark Meridian™ Filter System were manufactured at that facility. Defendants
20 further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and
21 that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™
22 Filter System. Defendants deny any remaining allegations contained in Paragraph 162 of
23 Plaintiff's Complaint.

24 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiff's
25 Complaint.

26 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's
27 Complaint.

1 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's
2 Complaint.

3 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's
4 Complaint.

5 **FIFTH CAUSE OF ACTION**

6 **BREACH OF EXPRESS WARRANTY**

7 167. Defendants incorporate by reference their responses to Paragraphs 1-166 of
8 Plaintiff's Complaint as if fully set forth herein.

9 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's
10 Complaint.

11 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's
12 Complaint.

13 170. Defendants deny the allegations contained in Paragraph 170 of Plaintiff's
14 Complaint.

15 171. Defendants deny the allegations contained in Paragraph 171 of Plaintiff's
16 Complaint.

17 172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's
18 Complaint.

19 173. Defendants deny the allegations contained in Paragraph 173 of Plaintiff's
20 Complaint.

21 174. Defendants deny the allegations contained in Paragraph 174 of Plaintiff's
22 Complaint.

23 175. Defendants deny the allegations contained in Paragraph 175 of Plaintiff's
24 Complaint.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

176. Defendants incorporate by reference their responses to Paragraphs 1-175 of Plaintiff's Complaint as if fully set forth herein.

177. Defendants deny the allegations contained in Paragraph 177 of Plaintiff's Complaint.

178. Defendants deny the allegations contained in Paragraph 178 of Plaintiff's Complaint.

179. Defendants deny the allegations contained in Paragraph 179 of Plaintiff's Complaint.

180. Defendants deny the allegations contained in Paragraph 180 of Plaintiff's Complaint.

181. Defendants deny the allegations contained in Paragraph 181 of Plaintiff's Complaint, including all sub-parts thereof.

182. Defendants deny the allegations contained in Paragraph 182 of Plaintiff's Complaint.

183. Defendants deny the allegations contained in Paragraph 183 of Plaintiff's Complaint.

184. Defendants deny the allegations contained in Paragraph 184 of Plaintiff's Complaint.

185. Defendants deny the allegations contained in Paragraph 185 of Plaintiff's Complaint.

SEVENTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

186. Defendants incorporate by reference their responses to Paragraphs 1-185 of Plaintiff's Complaint as if fully set forth herein.

1 187. The allegations contained in Paragraph 187 are conclusions of law, and no
2 answer is required. To the extent a response is required, Defendants deny the allegations.
3 Defendants any remaining allegations contained in Paragraph 187 of Plaintiff's Complaint.

4 188. Defendants deny the allegations contained in Paragraph 188 of Plaintiff's
5 Complaint.

6 189. Defendants deny the allegations contained in Paragraph 189 of Plaintiff's
7 Complaint.

8 190. Defendants deny the allegations contained in Paragraph 190 of Plaintiff's
9 Complaint.

10 191. Defendants deny the allegations contained in Paragraph 191 of Plaintiff's
11 Complaint.

12 192. Defendants deny the allegations contained in Paragraph 192 of Plaintiff's
13 Complaint.

14 193. Defendants deny the allegations contained in Paragraph 193 of Plaintiff's
15 Complaint.

16 194. Defendants deny the allegations contained in Paragraph 194 of Plaintiff's
17 Complaint.

18 195. Defendants deny the allegations contained in Paragraph 195 of Plaintiff's
19 Complaint.

20 **EIGHTH CAUSE OF ACTION**

21 **NEGLIGENT MISREPRESENTATION**

22 196. Defendants incorporate by reference their responses to Paragraphs 1-195 of
23 Plaintiff's Complaint as if fully set forth herein.

24 197. Defendants deny the allegations contained in Paragraph 197 of Plaintiff's
25 Complaint, including all sub-parts thereof.

26 198. Defendants deny the allegations contained in Paragraph 198 of Plaintiff's
27 Complaint.
28

1 199. Defendants deny the allegations contained in Paragraph 199 of Plaintiff's
2 Complaint.

3 200. Defendants deny the allegations contained in Paragraph 200 of Plaintiff's
4 Complaint.

5 201. Defendants deny the allegations contained in Paragraph 201 of Plaintiff's
6 Complaint.

7 202. Defendants deny the allegations contained in Paragraph 202 of Plaintiff's
8 Complaint.

9 203. Defendants deny the allegations contained in Paragraph 203 of Plaintiff's
10 Complaint.

11 204. Defendants deny the allegations contained in Paragraph 204 of Plaintiff's
12 Complaint.

13 205. Defendants deny the allegations contained in Paragraph 205 of Plaintiff's
14 Complaint.

15 206. Defendants deny the allegations contained in Paragraph 206 of Plaintiff's
16 Complaint.

17 **PUNITIVE DAMAGES ALLEGATIONS**

18 207. Defendants incorporate by reference their responses to Paragraphs 1-206 of
19 Plaintiff's Complaint as if fully set forth herein.

20 208. Defendants deny the allegations contained in Paragraph 208 of Plaintiff's
21 Complaint.

22 209. Defendants deny the allegations contained in Paragraph 209 of Plaintiff's
23 Complaint.

24 210. Defendants deny the allegations contained in Paragraph 210 of Plaintiff's
25 Complaint.

26 211. Defendants deny the allegations contained in Paragraph 211 of Plaintiff's
27 Complaint.

1 5. If Plaintiff has been damaged, which Defendants deny, such damages were
2 caused by the negligence or fault of Plaintiff.

3 6. If Plaintiff has been damaged, which Defendants deny, such damages were
4 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
5 not legally responsible.

6 7. The conduct of Defendants and the subject product at all times conformed to
7 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
8 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
9 part, under the doctrine of federal preemption, and granting the relief requested would
10 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
11 violation of the Supremacy Clause of the United States Constitution.

12 8. If Plaintiff has been damaged, which Defendants deny, such damages were
13 caused by unforeseeable, independent, intervening, and/or superseding events for which
14 Defendants are not legally responsible.

15 9. There was no defect in the product at issue with the result that Plaintiff is not
16 entitled to recover against Defendants in this cause.

17 10. If there were any defect in the products – and Defendants deny that there were
18 any defects – nevertheless, there was no causal connection between any alleged defect and
19 the product on the one hand and any damage to Plaintiff on the other with the result that
20 Plaintiff is not entitled to recover against Defendants in this cause.

21 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
22 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
23 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
24 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
25 either in whole or in part, from all persons or entities whose negligence or fault proximately
26 caused or contributed to cause Plaintiff's alleged damages.

1 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
2 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
3 at issue in a manner not intended by Defendants and over which Defendants had no control.

4 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
5 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
6 possession, custody, and control of Defendants.

7 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
8 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
9 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
10 Defendants.

11 15. Plaintiff's claims for breach of implied warranty must fail because the product
12 was not used for its ordinary purpose.

13 16. Defendants neither had nor breached any alleged duty to warn with respect to
14 the product, with the result that Plaintiff is not entitled to recover in this cause.

15 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
16 warnings and instructions to learned intermediaries.

17 18. At all relevant times, herein, Plaintiff's physicians were in the position of
18 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
19 benefits of the subject product.

20 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
21 entities for whose conduct Defendants are not legally responsible and the independent
22 knowledge of these persons or entities of the risks inherent in the use of the product and other
23 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
24 damages.

25 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
26 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
27
28

1 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
2 unknown, unknowable, or not reasonably foreseeable to Defendants.

3 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
4 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
5 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
6 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
7 damages that Plaintiff seeks to recover herein.

8 22. At all relevant times during which the device at issue was designed, developed,
9 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
10 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
11 information, and instructions, all pursuant to generally recognized prevailing industry
12 standards and state-of-the-art in existence at the time.

13 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
14 result of the alleged conduct and do not have any right, standing, or competency to maintain
15 claims for damages or other relief.

16 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
17 estoppel, and/or laches.

18 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
19 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
20 doctrines of contributory and/or comparative negligence.

21 26. In the further alternative, and only in the event that it is determined that
22 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
23 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
24 any other defendants, third-party defendants, or other persons, including any party immune
25 because bankruptcy renders them immune from further litigation, as well as any party, co-
26 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

1 27. Should Defendants be held liable to Plaintiff, which liability is specifically
2 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
3 from all collateral sources.

4 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
5 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
6 claims, and the prohibition on double recovery for the same injury.

7 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
8 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
9 over which Defendants had no control.

10 30. The conduct of Defendants and all activities with respect to the subject product
11 have been and are under the supervision of the Federal Food and Drug Administration
12 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
13 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

14 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
15 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
16 their Answer to file such further pleadings as are necessary to preserve and assert such
17 defenses, claims, credits, offsets, or remedies.

18 32. The device at issue complied with any applicable product safety statute or
19 administrative regulation, and therefore Plaintiff's defective design and warnings-based
20 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
21 comments thereto.

22 33. Plaintiff cannot show that any reasonable alternative design would have
23 rendered the Meridian™ Filter inferior vena cava filter device as alleged in Plaintiff's
24 Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f,
25 nor could Defendants have known of any alternative design that may be identified by
26 Plaintiff.

1 34. The device at issue was not sold in a defective condition unreasonably
2 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
3 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
4 comparable provisions of the Restatement (Third) of Torts (Products Liability).

5 35. At all relevant times during which the device at issue was designed, developed,
6 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
7 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
8 information, and instructions, all pursuant to generally recognized prevailing industry
9 standards and state-of-the-art in existence at the time.

10 36. Defendants specifically plead all affirmative defenses under the Uniform
11 Commercial Code ("UCC") now existing or which may arise in the future, including those
12 defenses provided by UCC §§ 2-607 and 2-709.

13 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at
14 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
15 Act.

16 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
17 grossly negligent, and, therefore, any award of punitive damages is barred.

18 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory
19 providing for liability without proof of defect and proof of causation, the claims violate
20 Defendants' rights under the Constitution of the United States and analogous provisions of
21 the Alabama Constitution.

22 40. Regarding Plaintiff's demand for punitive damages, Defendants specifically
23 incorporate by reference any and all standards of limitations regarding the determination
24 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No.*
25 *America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group,*
26 *Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513

(2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the Alabama Constitution, on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- (c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate

the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. The design complained of in Plaintiff's Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiff were not known and, in the light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

44. To the extent Plaintiff's Complaint alleges misrepresentation and fraud, these allegations do not comply with the requisite of particularity under applicable procedural rules and/or law.

45. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 10th day of December, 2015.

s/Richard B. North, Jr.
 Richard B. North, Jr.
 Georgia Bar No. 545599
 Matthew B. Lerner
 Georgia Bar No. 446986
 NELSON MULLINS RILEY & SCARBOROUGH, LLP
 Atlantic Station
 201 17th Street, NW / Suite 1700
 Atlanta, GA 30363
 PH: (404) 322-6000
 FX: (404) 322-6050
 Richard.North@nelsonmullins.com

James R. Condo (#005867)
 Amanda Sheridan (#005867)
 SNELL & WILMER L.L.P.
 One Arizona Center
 400 E. Van Buren
 Phoenix, AZ 85004-2204
 PH: (602) 382-6000
 JCondo@swlaw.com
 ASheridan@swlaw.com

**Attorney for Defendants C. R. Bard, Inc. and
 Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 10, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
Richard.North@nelsonmullins.com